

**Amendments to Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1-16. (Cancelled).

17. (Currently amended) A ~~kit~~combination for site-specifically transforming cells *in vivo* comprising a catheter and a nucleic acid comprising a gene encoding p21.

18. (Cancelled)

19. (Currently amended) The ~~kit~~combination of claim 17, wherein the catheter is a double balloon catheter.

20. (Currently amended) The ~~kit~~combination of claim 17, further comprising a pharmaceutical carrier.

21. (Currently amended) The ~~kit~~combination of claim 20, wherein the pharmaceutical carrier comprises a nucleic acid.

22. (Currently amended) The kit combination of claim 17, wherein the nucleic acid is an expression vector.

23. (Currently amended) The kit combination of claim 22, wherein the expression vector comprises a viral promoter.

24. (Currently amended) The kit combination of claim 23, wherein the viral promoter is a CMV promoter.

25. (Currently amended) The kit combination of claim 23, wherein the viral promoter is a RSV promoter.

26. (Currently amended) The kit combination of claim 17, wherein a viral particle comprises the nucleic acid.

27. (Currently amended) The kit combination of claim 26, wherein the viral particle is an adenovirus particle.

28. (Currently amended) The kit combination of claim 26, wherein the viral particle is a retrovirus particle.

29. (Currently amended) The kit combination of claim 17, further comprising a liposome.

30. (Currently amended) The kit combination of claim 29, wherein the liposome comprises the nucleic acid.

31. (Currently amended) The kit combination of claim 17, wherein the nucleic acid comprises a second gene.

32. (Currently amended) The kit combination of claim 31, wherein the second gene encodes HLA-B7, an immunotherapeutic agent, cytokine, or prodrug converting enzyme.

33. (Currently amended) The kit combination of claim 32, wherein the prodrug converting enzyme is thymidine kinase.

34. (Currently amended) The kit combination of claim 31, wherein the gene encoding p21 and the second gene are operatively linked.

35. (Currently amended) The kit combination of claim 34, wherein the gene encoding p21 and the second gene are operatively linked such that they form a fusion protein.

36. (Currently amended) The kit combination of claim 35, wherein the gene encoding the fusion protein is a p21-thymidine kinase fusion protein.

Application Number 09/663,889

37-54. (Cancelled)

## REMARKS

Claims 17, and 19–36 are pending.

Claims 1, 18 and 37–54 are cancelled.

## AMENDED CLAIMS

Claims 17 and 19-36 are amended without prejudice or disclaimer of the subject matter claimed therein to recite the combination of a nucleic acid comprising a gene encoding p21 and a catheter. No new matter is added in these amendments. The amendments are supported by the specification at page 14, lines 18-20 and page 19, lines 3-6.

## PRIORITY

Applicants' claim of priority of U. S. Serial Nos. 08/533,942, 09/031,572 and 09/426,325 stands denied. The Examiner alleges that the application adds and claims additional disclosure not presented in the prior applications.

The Applicants respectfully disagree with the Examiner's interpretation of *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). However, to advance prosecution, Applicants have amended the claims to recite the combination of a nucleic acid comprising a gene encoding p21 and a catheter.

The combination of a catheter and a nucleic acid encoding p21 for site-specific instillation of cells is shown in U.S. Patent Number 5,863,904 (U. S. Serial No. 08/533,942) at column 6, lines 51-53 and column 8, lines 36-38; in U.S. Patent Number 6,057,300 (U. S. Serial No. 09/031,572) at column 6, lines

Application Number 09/663,889

49-51 and column 8, lines 36-38; in U.S. Patent Number 6,218,372 (U. S. Serial No. 09/426,325) at column 6, lines 49-51 and column 8, lines 55-58; and in the present application at page 14, lines 18-20 and page 19, lines 3-6. Accordingly, Applicants respectfully request that the Examiner withdraw denial of priority.

#### **OATH/ DECLARATION**

The Examiner alleges that the present application presents a claim for subject matter not originally claimed or embraced in the statement of the invention and requires a new oath/ declaration. Applicants submit that the above amendments overcome this requirement. For this reason, Applicants respectfully request withdrawal of the Examiner's request for a new oath/ declaration.

#### **35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS**

Claims 17-36 are rejected under 35 U.S.C. §112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants submit that the above amendments overcome this rejection. As discussed above with respect to Applicants' priority claim, the present application, at page 14, lines 18-20 and page 19, lines 3-6, discloses a combination of a catheter and a nucleic acid encoding p21. Applicants request withdrawal of the Examiner's 35 U.S.C. §112, first paragraph rejection for the reasons stated above.

**CLAIM REJECTIONS UNDER 35 U.S.C. §102**

Claims 17 and 19–36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nabel *et al.* (U.S. Patent No. 5,863,904) (“the ‘904 patent”).

Applicants respectfully traverse the Examiner’s rejection. In view of the arguments made above with respect to the priority of the instant application, Applicants submit that this application is entitled to a priority date of September 26<sup>th</sup>, 1995. Accordingly, the ‘904 patent, which issued on Jan 26, 1999 cannot anticipate the present claims because it was not published more than one year prior to the priority date of the present application. Applicants therefore request that the Examiner withdraw the 35 U.S.C. §102(b) rejection of claims 17 and 19–36.

Favorable consideration and allowance of this application are respectively requested for the reasons set forth in the above remarks. If, for any reason, the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Dated: August 5, 2003

John Murray

John Murray, Ph.D.  
Registration No. 44,251  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
Telephone: (312) 321-4229